UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRAINTREE LABORATORIES, INC. and SEBELA US INC.,

Plaintiffs,

v.

LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,

Defendants.

CIVIL ACTION NUMBER:

23-cv-2853-CPO

SCIENCE DAY PRESENTATION

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
October 15, 2024
Commencing at 12:06 p.m.

B E F O R E: **THE HONORABLE CHRISTINE P. O'HEARN, UNITED STATES DISTRICT JUDGE**

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(Proceedings held in open court before The Honorable Christine P. O'Hearn, United States District Judge, at 12:06 p.m.)

THE COURTROOM DEPUTY: All rise.

THE COURT: Okay. Please be seated. We're on the record in the matter of Braintree Laboratories vs. Lupin Limited, 23-cv-2853.

May I have appearances of counsel, starting with plaintiffs.

MR. MILLER: Good afternoon, Your Honor. Keith Miller from the law firm of Robinson Miller, Newark, New Jersey, for the plaintiffs.

Also with me are my co-counsel from Wilmer Hale, Christopher Noyce.

MR. NOYCE: Good morning, Your Honor.

MR. MILLER: Lisa Pirozzolo.

MS. PIROZZOLO: Good morning, Your Honor.

MR. MILLER: Gabe Rosanio.

MR. ROSANIO: Good morning, Your Honor.

MR. MILLER: And Lauren Matlock-Colangelo.

MS. MATLOCK-COLANGELO: Good morning.

THE COURT: Good morning. And for defendants?

MR. RICHTER: Good afternoon, Your Honor. James Richter from Midlige Richter on behalf of Lupin.

And with me today are my co-counsel from the Knobbe

Martens firm, William Zimmerman and Brian Barnes.

THE COURT: Thank you everyone for coming early. I will tell you that I have a criminal matter that I have to cover for the Chief at 1:30, so hopefully that may come between the break of your presentations. And if not, we'll break at an appropriate time.

And I'll just ask you to step back. It's a non-detained defendant, he'll come forward, I'll take the plea. You're welcome to leave the courtroom. It will take me 30 minutes, and then we'll finish. I apologize. But it's a criminal matter and it has to be done today.

But thank you for coming in. Just give me one second.

(Brief pause.)

THE COURT: Okay. I have all your briefs. Is plaintiff ready to proceed?

MR. NOYES: We are, Your Honor.

THE COURT: All right. Thank you.

MR. NOYES: And, Your Honor, I have some printed copies of slides, if that would be helpful.

THE COURT: Okay. Great.

MR. NOYES: And may I approach, Your Honor?

THE COURT: Yes.

MR. NOYES: May I proceed, Your Honor?

THE COURT: Yes.

MR. NOYES: And let me just say one thing. With

respect to the slides that I just handed out, they do have -- we were overzealous. They were marked as attorney-client privilege. These obviously are not attorney-client privilege. We're happy to replace the slides if Your Honor would like replacements.

THE COURT: I'm going to write all over my copy and I'm the only one that's going to see it, so it's okay.

MR. NOYES: Thank you. And I conferred with Mr. Zimmerman from Lupin as well.

So, Your Honor, we're here for science day to present a technology tutorial about the technology related to these patents. And again, my name is Chris Noyes, and together with my colleagues we'll be presenting today. I'm going to start, Your Honor, talking about some of the background of the technology, and then Ms. Pirozzolo is going to finish the presentation talking about specifics related to the technology and the asserted patents.

THE COURT: Okay.

MR. NOYES: Now, Your Honor, this is a Hatch-Waxman case and it's about Braintree's bowel prep called SUTAB and the Orange Book patents that cover the product. And SUTAB is an osmotic laxative. It's a specific type of laxative. It's FDA approved for cleansing of the colon in preparation of colonoscopy.

And bowel preps, like SUTAB shown here, are necessary

for an effective colonoscopy, and that's important because colonoscopy is essential for the detection and prevention of colon cancer.

And just briefly, Your Honor, I'm going to walk through colon cancer at a high level screening and detection and osmotic bowel preps, and then Ms. Pirozzolo will talk about technology of the asserted patents.

Now, Your Honor, in the United States, colon cancer is the second most common cause of cancer death to this day. Over 50,000 deaths caused by colon cancer in 2023. And it's one of the leading causes of cancer death for people under 50 years old. It's the leading cause for men under 50 and the second leading cause for women under 50 years old.

The American Cancer Society estimated in 2023 that over 150,000 people would be diagnosed with colon cancer, and it estimated that it would kill over 50,000 people, including thousands of people actually younger than 50 years old.

And Your Honor, as colon cancer prevalence has increased, the recommendations for when people are screened with colonoscopy has decreased, so now the recommendation is that anyone age 45 and older get screened for colonoscopy. It used to be 50 and older.

The American Cancer Society has also identified increasing access to high-quality screening as the number one way to achieve progress against colon cancer.

Now, just a very brief background of gastrointestinal anatomy before we get into the technical details. And this is how the GI tract works. You see the stomach, of course digests food; it turns it into this liquid slurry; and then that liquid slurry moves from the stomach into the small intestine, which is in the middle there, sort of the flat smaller tube. In the small intestine, the body absorbs vitamins, minerals, and other nutrients. And as the nutrients are absorbed, whatever is left over, the waste product, moves into the colon, which is the larger bumpy organ shown here.

The colon is about six feet long. And that's the organ in this case, the colon, that we're primarily concerned with. Once the liquid slurry gets into the colon, the body absorbs whatever water is left to make hard stool, and then the stool obviously gets -- moves into the rectum for expulsion.

Now, colon cancer screening. Colon cancer starts with a polyp generally on the inner lining of the colon. And they start off as a result of what's called hyperproliferation of cells, and they look like these small, mushroom-shaped polyps on the inner lining of the colon. And it's not just polyps, actually. Sometimes it could be very flat, almost lesion-like growths that can result in colon cancer.

So removing these polyps at an early stage when they're benign can prevent the development of cancer. And the five-year survival rate is about 75 to 90 percent if these

polyps are identified in their benign stage. But if a polyp is not removed and continues to grow, you can see here, it becomes malignant and turns into colon cancer, and that develops -- that causes fatalities.

As these polyps continue to develop, they become malignant, and the survival rate drops to 40 percent. And then when you get to the Stage 4, the latest stage, only five percent survival rate. So again, early detection, finding the polyps is the most important thing to preventing colon cancer.

And screening is the major way to reduce colon cancer deaths. But it's really underused. It's actually still underused today. Researchers from the University of Pennsylvania and Memorial Sloan-Kettering determined that 63 percent of colon cancer related deaths in 2010 were caused by non-screenings, people just didn't get screened, and that's why they were dying. And that means that screening could have saved the lives of over 32,000 people in 2010 alone.

Now, increasing screening has been the goal for researchers in this space because increasing screening for people 45 and older, especially those with risk factors, has tremendous potential health benefits.

Now, colonoscopy, Your Honor. This is just a picture of the colon and how colonoscopy works. It's the gold standard still to this day for detection. You may have seen ads for Cologuard and things like that on TV, which is a DNA test. But

at the end of the day, even if you do take one of these DNA tests, you have to get a colonoscopy if you come up -- if it's a suggestion that you have colon cancer.

And this is a -- the colonoscope is inserted into the colon and it has a camera at the end, and it has this little snare at the end as well so it allows the doctor to identify polyps or other cancerous lesions and then to remove them with this snare.

And colonoscopies at bottom require a clean colon to work. If the colon is not sufficiently clean, waste and other debris can obscure the doctor's ability to see, find, and detect polyps.

And you could compare this to driving down a road, for example, with fog. You might not see potholes, you can't see the view, you can't see the road signs and that could be dangerous. And colonoscopy is -- not being able to see could be extremely dangerous because the doctor can't find polyps. They could be in that long six-foot organ, they could be hiding in the various cracks and crevices. And if they're not identified, a couple years go by after your screening, and they can obviously turn into malignant cancers.

The other thing about insufficient cleansing is that the patients will come for their colonoscopy, they're both in this prep process, which we'll talk about, which is, as you'll see, a very unpleasant process. And one of the big major

barriers of colonoscopy, they have to be rescheduled. And a lot of times people are out of work, they don't come back for screening. They don't get the second screening if they're rescheduled, and so they go years without being screened for colon cancer. And that obviously can cause polyps to develop into malignant cancers.

Now, in many cases it's stool in the colon that isn't flushed out from the prep that causes inadequate visualization, but some of these bowel preps also can be too cloudy, they can be too shiny, and that also can impede visualization.

So it's not just how well the bowel prep works, it's all how it's made, what are the components that are important for adequately -- for adequate prep and clear colons.

Now, unfortunately, even with all the advancements and colon preps which we'll talk about, as of 2020, doctors were still seeing about 15 to 35 percent of inadequately prepared colons during colonoscopy procedures. So the bottom line is, you need an adequate prep for a colonoscopy; you need to be able to see in the colon and to identify and remove polyps. And without that, we're not going to be making much progress against colon cancer.

But historically, Your Honor, the prep has been a major barrier to colonoscopy --

THE COURT: I want to know who are the 45 percent of the people who think it's not the worst part.

(Laughter.)

THE COURT: Because I was able to evade during COVID for several years until last year, so I'm very curious as to who the other 45 percent are.

MR. NOYES: Right. I ask that question myself.

THE COURT: Some of you are not 50 yet, I can see, but some of us are, so I'll just leave it at that.

MR. NOYES: Yes. It is interesting, who are the 45 percent who say that's not the worst part?

But yes, a vast majority of the people believe, and the studies have shown this, that it is the worst part of colonoscopy and it's the biggest deterrent to getting a colonoscopy. People just don't want to take the prep, and for two reasons, which we'll talk about.

Many of them are in this big, large volume. These are the original preps from the early '80s. They're still available today. They're called 4-liter preps. People just can't drink that much liquid or it's made up of sort of a salty liquid, there's electrolytes in them, they just can't consume that. And of course, the effects of this obviously are unpleasant for people as well.

So we have this double whammy where you can't drink the prep, take the prep, and you don't like to experience the prep, causes you to do, and so people just are not complying with the prep and that results in an inadequate preparation for

colonoscopy.

Now, over the years, Your Honor, there have been many FDA-approved products for bowel preps, and here's a timeline through 2020. And there's actually some FDA-approved ones after 2020. But Braintree has been an innovator in bowel prep since the early 1980s, and Braintree was a small company that was founded in Braintree, Massachusetts, thus the name, Braintree Labs. And in 1984, they received FDA approval for GoLYTELY, which was essentially this 4-liter volume prep.

And we have a key here on the slide for Your Honor. These original 4-liter preps were made up of something called polyethylene glycol or PEG, and that polyethylene glycol was used to flush the colon, and we'll get into how that worked in a moment.

But those are the 4-liter preps that forced patients to drink all of this liquid to have an adequate prep. And you can see over the years Braintree has continued to develop new preps. There was the NuLYTELY prep in the early 1990s, that was also a 4-liter PEG-based solution that had some flavoring. They added a lemon packet to make it more palatable, but still not palatable enough.

And then in the early 2000s, they came up with HalfLytely, which was actually a 2-liter, so half of this, half a gallon, and continued to innovate. We'll talk about these different preps.

Starting in 2010, Braintree introduced SUPREP to the market, which is a small volume, 16 ounces, a different type of prep. You see here it has sulfate salts. And then in 2020 is when the FDA approved SUTAB, which is the product at issue in our case, which is sulfate salt based prep but in a tablet form.

And below the Braintree products are products that were developed and introduced by other companies, which we'll talk about, PHOSPHO-SODA, VISICOL, and OsmoPrep. And as you can see, those were all phosphate salt products. And that phosphate salt allowed these products to be very small volume prep, so not the large volume, but they ended up being effective, but extremely dangerous, and I'll talk about that in a moment.

And then finally, there's a product on the market now that's competing with SUTAB, an FDA product called CLENPIQ. And that, as you see here, is a picosulfate liquid. Now, picosulfate, that's not really relevant for purposes of today, but that's a different chemical. That's called a stimulant laxative, and it actually is not related to the sulfate salts that are in SUTAB. It's just a different chemical composition.

Now, one of the things that's very important in preps and bowel preps is the concept of electrolytes in the body, and this is just a very simple example. Electrolytes are essentially salts dissolved in water. So the table salt

example, solium, chloride, and ACL. You put in water and it breaks up into two different ions, one sodium and one chloride. And we have all these electrolytes in our body. Our body is -- 60 percent of our body is made up of water and we have these dissolved electrolytes in our body.

And those are all important, very important to different body functions. And we have a slide on that. We are going to talk about that in a moment.

But they are essential to different important body functions and there's a range that they need to be in for a healthy person to be operating -- to be healthy. And things like exercise, diet, medications like bowel preps can alter the balance of electrolytes in the body.

Now, another concept that you'll hear about, Your Honor, that relates to how these bowel preps work is this concept of tonicity, and that is a measure of osmotic pressure in a solution. And then osmotic pressure basically is you have two different solutions with different salt concentrations.

So for example here, you have sea water, high salt concentration; and then you have distilled water, lower salt concentration. The sea water is called hypertonic and then the distilled water is called hypotonic. And what happens here is you have a membrane like a filter or a cell wall, for example, semipermeable membrane. So certain things can pass the membrane but not everything. There's something called osmotic

pressure, which is trying to achieve equilibrium between these two concentrations. So essentially you want the same amount of salt in both, the salt water and the distilled water.

And so the sea water here will pull water from the distilled water into the sea water in this example, causing the sea water to be more dilute, less concentrated. And that's just the scientific phenomenon. And that's that concept of osmotic pressure that has been used in bowel preps like SUTAB in our case, and previous preps, and we'll talk about more of those in a moment.

But how they do this is they use these poorly absorbable salts called osmotic agents, like sulfate salts or phosphate salts. And when those get in the colon -- and here's an example. When they're in the colon, what they do is they pull water from the body into the colon. And so that's what's actually flushing the colon. The water is pulled from the body into the colon, that water softens the stool and causes the purgation, the diarrhea that's necessary for colon cleansing.

On the left-hand side you'll see what these larger-volume products called isotonic solutions. So they don't use the water in the body. That's why you have to drink so much of it. Right? You just are flushing the colon with the liquid in the prep.

So you'll hear about hypertonic solutions, you'll hear about isotonic solutions, and you'll hear about osmotic agents

and osmotic pressure in this case because that's the mechanism of action that's making these products work.

And just very briefly, Your Honor, there's an impact on cells on the body when you're using hypertonic solution. The water has to come from somewhere. So what it does is it actually takes the water out of the body and the cells can be dehydrated. So not only are you getting dehydrated cells, you're pulling electrolytes out of the body and those also get flushed out.

And so when researchers are trying to develop these colon preps, they're trying to make them work really well, they're trying to get patients to comply to take them, but they're also trying to avoid electrolyte imbalance and fluid shifts, dehydration. So those are all the considerations that the researchers are working with when they're trying to make bowel preps.

So now, the bowel preps, we talked a little bit about this already. We have the GoLYTELY and the NuLYTELY, which are these 4-liter preps; these are the isotonic ones, you're just flushing the colon; and then there was the further development of the 2-liter prep. These worked essentially this way, Your Honor, and this is a very simplified diagram. But you have colon, stool in the colon before ingestion, and then you have your body water. You drink all of this liquid prep, and then -- the prep not only has the PEG in it, which can't be

absorbed, but it also has some electrolytes in it. And what happens is it flushes the colon and the multiple instances of diarrhea, so by the end the goal is to have a clear liquid and all the stool is out of the body.

The body water, though, remains the same because you haven't pulled any water from the body, or very little water from the body into the colon and the electrolytes' balance stay the same because these products had electrolytes, that's why they're salty, to replace what was being flushed out.

Now, these are very safe products. They're still available. People still use them. Doctors still prescribe them. But again, the patient compliance is a huge issue with these. And a lot of times people will drink half the dose, three-quarters of the dose, have one, you know, instance of diarrhea and say I'm done, I'm just not doing it. And then they go to the doctor, and the doctor either says -- you know, they might miss a polyp or they reschedule them for another colonoscopy.

So because of this, there are other researchers trying to solve the problem. They said, how do we come up with a small-volume prep? And here's two examples that became very poplar after the large-volume preps were on the market.

One was called Fleet PHOSPHO-SODA and the others were called VISICOL and OsmoPrep. These both were smaller-volume preps. You can see the Fleet was essentially 45 milliliters

total that you took, so a lot smaller. These preps all used phosphate salts. And they were very effective and patient compliance was very good because the volume was so low.

The problem with these preps -- and let me just briefly describe how these worked. And again, talked about this already, but these preps work by the osmotic agent phosphate, creating that osmotic pressure, pulling water into the colon and then it will soften the stool and things will get flushed out. Body water will get flushed out and electrolytes will get flushed out as well.

And here's an example of how these would work. You see here you have electrolytes in your body, in your intestine, in your colon, and you have your body water. You ingest Fleet, for example, that would result in effective cleansing, but what would happen is you lose body water, you lose almost a gallon of water from your body when you took Fleet.

And another problem with this particular formulation was it didn't have electrolytes in it to replace the electrolytes that were being lost from the body. And in fact, with PHOSPHO-SODA, the majority of potassium in the body was lost when patients were taking this. And as I mentioned before, that's a really important thing because electrolyte imbalances can cause medical conditions.

And just pausing on potassium here, for example, it's essential for blood pressure, heart function, muscle function.

And if you lose it, it's called hypokalemia, loss of potassium. You could have kidney damage, muscle weakness, dizziness, loss of consciousness, et cetera, arrhythmias. And there's some other examples here, Your Honor, about how electrolytes are required for important body function and how loss or too much of those things can impact the health of people.

Now, the thing about Fleet was not only was it causing loss of water, loss of electrolytes, it was actually killing people. And it was recalled -- the FDA issued a warning in 2008. You can see here the product was actually recalled because of serious side effects including destruction of the kidneys. Essentially it would deposit calcium and phosphate in the kidneys and it was called nephrocalcinosis, it calcified people's kidneys. And so Fleet was taken off the market.

And then there was a black box warning in the label for VISICOL and OsmoPrep, you can see it here. These cases resulted in permanent impairment of renal function and some patients required long-term dialysis. So it turned out these products were very unsafe at the end of the day and they were taken off the market. They have all been discontinued at this point.

Now, in -- so that was 2008 when the FDA said we have a problem with these small-volume preps. And in 2010, the FDA approved another -- a different type of small-volume prep and this was -- you can see the difference here, Your Honor. This

was SUPREP and here's what the bottle was. So you take two of these, 16 ounces of these plus additional water. And this didn't have phosphates. This had sodium sulfate, potassium sulfate and magnesium sulfate, and those were the osmotic agents like sodium phosphate but they didn't result in the electrolyte problems, in the kidney damage problems of the Fleet.

So -- and just briefly, Your Honor, this is how SUPREP worked and still works today. You see here the -- again, there's electrolytes and there's stool in the colon and you have your body water. The prep itself has a balance of sulfate salts that replace electrolytes that were lost. It's a smaller volume. It does bring body water into the -- it does use the body's water to flush the colon, but as part of the dosing regimen you're drinking additional water to avoid dehydration. And then the prep itself is balancing the electrolytes.

So that was a very safe prep, a smaller-volume prep. Still, though, there were compliance issues because you can imagine highly concentrated sulfate salts are not palatable for many people. They try to mask these with -- I forget which flavor this was. This was lemon lime or orange or something like that. But many people found them to be unpalatable and you're still having compliance issues, even with SUPREP, which was one of the most successful preps around.

So we're still left with a situation where you need an

effective prep that gives you sufficient cleansing for adequate visualization of the colon, one that's safe, no electrolyte disturbances that are dangerous, no dangerous fluid shifts, no kidney damage but doesn't require patients to ingest all of this liquid, all of this amount of -- or unpleasant tasting liquids.

And that's where we end up for this case, Your Honor, the SUTAB, which are -- if you look here, it's a split-dose regimen. So you take 12 pills the night before the colonoscopy and then you take 12 pills the morning of. And the only thing you're required to drink is water. And so this has potassium chloride, sodium sulfate, and magnesium sulfate in it. Again, that induces the purgation by using an osmotic agent, brings the body water into the colon, but it's an imbalanced solution that replaces electrolytes and when you're drinking the water, you're not getting dehydration.

So that's the background and probably a very too quick history of colon preps, but now I'm going to turn it to Ms. Pirozzolo and she's going to talk more about the patents and how this technology relates to the patents.

THE COURT: Thank you.

MS. PIROZZOLO: Thank you, Your Honor. Lisa Pirozzolo for the plaintiffs.

I would like to briefly discuss the asserted patents in this case. They all claim priority to a 2017 patent

application and they're all directed to solid oral sulfate salt formulations for cleansing the colon.

As the abstract of the patents explains, the patents disclose these solid oral dosage formulations that comprise sodium sulfate, magnesium sulfate, and potassium chloride for colon cleansing. Two of the patents, the '656 and the '697 Patents claim formulations for colon cleansing; and the other two patents, the '498 and the '864 Patents claim methods of colon cleansing.

Before we go through the claims, I was going to walk through some of the important parts of the specifications. And the specifications you'll see have the background at Columns 1 and 2, a summary of the invention at Columns 2 to 5, a detailed description of the invention and then examples. So I'm going to touch on aspects of the specification.

So in the detailed description, as discussed at Column 7, the claimed formulations are tablets that contain three -- these three salts: Sodium sulfate, magnesium sulfate, and potassium chloride.

The combination of these salts was developed to induce hypertonic colon cleansing, as Mr. Noyes described a few minutes ago. The formulation was also designed to work without causing the clinically significant electrolyte shifts that Mr. Noyes discussed and the other adverse effects that some of the phosphate-based formulations had experienced.

And so these concepts: The combination of salts, the avoiding electrolyte shifts, clinically significant electrolyte shifts, and other side effects as discussed in the specification.

So if -- as to the specific combination of salts, I've put up a section of Column 2 of the patent, and this section of the patent describes the specific combination of salts. And you can see the sodium sulfate in the blue box, magnesium sulfate in the purple box, and potassium chloride in the green box. And the specification describes the specific amounts of these salts that have to be in the formulation for it to have the right effects.

So it's about 30 to about 40 grams of sodium sulfate, about 4 to 8 grams of magnesium sulfate, and about 3 to 5 grams of potassium chloride. And then the spec described narrows that down to more specific formulations with more specific quantities of the three salts.

This specific combination of salts, as explained in Column 5 of the patent, had two particular benefits. First, the inventors discovered that only two sulfate salts, the sodium and magnesium sulfate, were required for colon cleansing.

Second, the inventors discovered that including potassium chloride along with the magnesium and sulfate salts could avoid this problem of clinically significant electrolyte

shifts. So when you combined the magnesium sulfate, the sodium sulfate, and the potassium chloride in the amounts specified in the specification, that would induce diarrhea, the purgation you want for your colonoscopy, but it would reduce the clinically significant gains or losses of electrolytes that could be harmful to patients.

And so this specific combination was important. And I think Mr. Noyes has already covered this, but in terms of colon cleansing, the specification explains at Column 5 how this works, that the sulfate salts are poorly absorbed and so they remain in the colon and they create this osmotic pressure that, if you call the sea water and the fresh water, it causes the water to enter the colon and induce purgation. So that's how the formulation effectively cleanses the colon.

But in addition to effectively cleansing the colon, this combination addresses the two shortcomings in the prior art that Mr. Noyes discussed. So the medical dangers caused by the clinically significant electrolyte shifts and also the renal failure that had been caused by the phosphate-based formulations.

So in terms of the clinically significant electrolyte shifts, you know, we've talked about it, but by including this specific balance, you keep kind of the electrolytes in the body properly aligned.

And secondly, the inventors discovered you didn't need

to include phosphates such as been included in those other colon preps that Mr. Noyes discussed, the one with the black box labels. You could have effective colon cleansing without using phosphates.

So that is kind of how these formulations work and why the combination of active ingredients is so important.

I wanted to shift to another important aspect of the invention, which is the fact that these are in tablet form. And the specification explains at Column 5 that the tablet formulations include both active ingredients and inactive ingredients. The sodium sulfate, magnesium sulfate, and potassium chloride we've been discussing are the active ingredients in the formulation, and they're called active ingredients because those are the ingredients that induce the purgation of the colon and create the osmotic effect and balance the electrolytes.

But the tablet formulations also include inactive ingredients known as excipients that are necessary to actually put these active ingredients into tablets that could be used. And so it's these excipients that enable the tablet formulation.

So in the Examples section of the patent you'll -- the inventors describe specific formulations that they made. So for example, Table 1 of the specification shows three specific formulations that the inventors made. And you can see in

Table 1, in these examples, specific amounts of active ingredients and inactive ingredients.

The three active ingredients that we've discussed are discussed at the top in blue, purple and green, but then there are two inactive ingredients or excipients that were in these formulations that are in red and orange below. And I'll talk about those a little bit.

So excipients can do different things in a tablet. We have a picture of a tablet here. Tablets have an inside, a coating. And these excipients do different things to make the tablet work.

For example, the patent talks about the use of lubricants in making tablets. Lubricants are excipients that facilitate the tableting process and make it easier for the tablet to be ejected from the tablet machinery. And as the asserted patents discuss in Column 7, which we have here, sodium caprylate is one example of a lubricant that can be used in the tablets. And that is, in the Table 1, one of the inactive ingredients was NaCaprylate, and that is the excipient being referred to there.

The patents also talk about binders. And binders are the glue that holds the different tablet components together. The asserted patents explain that the binder could be Polyethylene Glycol 8000 or PEG 8000, and that is the other excipient that was referred to in Table 1 of the patent that we

looked at.

In this context, PEG is being used differently than it was being used in some of the other colon cleansing preparations that Mr. Noyes talked about. In those it was used in large amounts to induce purgation; here it's being used in a small amount as an excipient and not as an active ingredient.

So another aspect of excipients that was important to the invention was that the properties of these excipients matter when you're putting together an effective colon cleansing prep.

Mr. Noyes talked about the importance of being able to visualize the colon during the colonoscopy procedure. Because the colon contains a lot of water, it's important for visualization, for these tablets to dissolve effectively in the colon. So you don't want the tablets to leave -- to have particles or leave an oily residue in the colon because that could impede the efficacy of the colonoscopy.

So the inventors explained in the specification that the claimed formulations use a minimal amount of water-soluble excipients and that's so that they'll dissolve clearly and not leave an insoluble residue in the colon when you take the preparation.

So just a little more on dissolution. The patents discuss the quick dissolution of the tablets, including the excipients in the water of the colon in order to facilitate the

visualization. And the dissolution characteristics can be evaluated using an apparatus where you put a tablet in a given amount of solution and you have a paddle, swirl it around. And this can then be measured and it's called dissolution testing. And the patent describes that at Column 9.

The patents also talk about the concept of turbidity in Column 9, in the same portion where dissolution is discussed that I just referred to.

THE COURT: Can you say that again? I am sorry. Also refers to what?

MS. PIROZZOLO: Turbidity.

So turbidity refers to the cloudiness or haziness of a fluid. And turbidity can occur for several reasons, including the compound leaving an oily residue. So turbidity can also be measured in a formulation using a device that measures how much light is scattered as the solution -- as it passes through the solution. And this is described in the patent at Column 9.

And the units used are Nephelometric Turbidity Units or NTUs. The higher the NTU value, the more light scattering has occurred and the more turbid or cloudy the solution is.

So another key aspect of the invention is the ability to use large amounts of active ingredient as compared to these inactive excipients we're talking about. So on the screen are these tablets and the actives are in green and the excipients are in blue.

And the goal of the patent -- the patents discuss reducing the excipients to as little as 10 percent or even as little as 5 percent of the total weight of the tablet, and having the active ingredients be in the neighborhood of at least 60 to as high as 80 -- I am sorry, the sodium sulfate active ingredients to be as high as 80 percent of the tablet.

And the significance of this ratio of excipients to active ingredients is important because it allows the tablets themselves to be smaller and the number of tablets the patients take to be smaller. And the idea is you're coming up with a way to maximize the amount of active ingredient going into the patient and minimize the amount of inactive ingredient to try to make the tablets more compact and fewer and reduce the burden on patients.

So the claimed tablet formulations are in order to be more convenient for the patients and the patent talks about this. In addition to having these tablets that are manageable size and quantity, you can drink water with the tablets so you don't have to drink the salty tasting, kind of bad smelling preparations that people really dislike.

The claimed -- this fact describes how you can take a total of 24 tablets in a split dose of 12 so that it's making it manageable with these two administrations for patients to get the entire dose taken with water. And by reducing the barriers to compliance, the goal is to get more effective

colonoscopy prep for patients.

So those are some of the highlights of the spec, and I was going to briefly just go through the claims of the patents that are being asserted here.

The '656 Patent is one of the formulation patents I mentioned. The asserted claims are 1, 3, 8, 9, 11, 17, 18, and 20. And the claims are directed to these formulations with the three salts I mentioned. So the claims have sodium sulfate in blue, magnesium sulfate in purple, and potassium chloride in green.

And they have ranges for the amounts of those ingredients in the claims. The claims also, if you look at Claim 3, recite that that formulation of those salts is compressed into tablet form. Claim 8 -- in a tablet of 24 tablets, that's Claim 3. And then Claim 8 specifies that those tablets can be divided into two doses with each dose being 12 tablets, that's in Claim 9.

And Claim 17 and 18 talk about the dissolution characteristics of the formulation, and Claim 20 talks about the turbidity of the formulation as measured in the NTUs. So that's the claims that are being asserted in that '656 Patent.

The '697 Patent is the other composition patent, and the main difference between the claims that are being asserted there and the claims of the '656 Patent are that if you look at Claim 1, there are more specific amounts of the three active

ingredients. So 35.5 grams of sodium sulfate, 5.4 grams of magnesium sulfate, and about 4.5 grams of potassium chloride.

And this patent also recites the sodium caprylate excipient, this patent in Claim 4. And in Claim 5 it specifies the PEG excipient is PEG 8000, which is a specific type of PEG.

The '498 Patent is one of the method of administration patents. This patent basically claims administration of the formulation and specifies administering the active ingredients with water. And claim -- the '864 Patent further describes the dosing regimen and specifically mentions the PEG excipient component.

So those -- that's a high-level review of the specification and the claims.

And just to wrap up, these four patents are listed in the FDA's Orange Book for SUTAB, so they cover the SUTAB product that Mr. Noyes mentioned, and SUTAB was approved on November 10th, 2020.

So if Your Honor doesn't have any questions -- or do you have questions?

THE COURT: Not yet. I am a lawyer, right? I am not a scientist. I say I went to law school because I can't do science or math. But when we have these days, I learn more than I think I ever learned or thought I would learn as a

lawyer.

But no, very helpful. Thank you very much.

How long do you think -- is that the total of your presentation, I'm assuming, because you're at the end of your slides?

MS. PIROZZOLO: Yes.

THE COURT: How long do you think you'll be? An hour?

MR. ZIMMERMAN: I believe I'm 45 minutes, Your Honor.

THE COURT: So what I'm going to do -- because I was supposed to do the criminal matter at 1:30. And if that's the case, I will just make them wait 15 to 20 minutes rather than breaking and make you wait.

MR. ZIMMERMAN: I'm happy to begin.

THE COURT: So if that's the case, then I think that makes the most sense.

MR. ZIMMERMAN: Your Honor, we also have some slides. May I approach?

THE COURT: Yes.

MR. ZIMMERMAN: May I proceed, Your Honor?

THE COURT: Yes.

MR. ZIMMERMAN: Bill Zimmerman of Knobbe Martens on behalf of the Lupin Defendants.

I think the good news is that the parties seem to agree on a lot of the relevant background and the key issues for today.

If we could go to the next slide.

This case relates to Lupin's filing of an Abbreviated New Drug Application which seeks to market a generic version of plaintiffs' SUTAB product. SUTAB is an osmotic laxative for cleansing the colon before a colonoscopy. And as you heard, it has three key active ingredients that we'll be discussing, all of which are salts: Sodium sulfate, magnesium sulfate, and potassium chloride.

There are four asserted patents. They're all from the same family, they all have the same specification. The only difference is in the claims.

If we could go to the next slide.

As you heard from Mr. Noyes, the colonoscopy is a very common procedure that's used to screen for GI diseases and colon polyps, which can lead to cancer. The procedure involves imaging the colon with a small camera. And because of the nature of the procedure, it's important that the colon be cleansed of fecal matter prior to the colonoscopy and you need to be able to clearly visualize the lining of the colon. That's the key part to be able to detect the disease and the polyps.

And the figure on the slide is illustrative of what the difference is between kind of pre-cleansing and post-cleansing. And you can see from the picture on the right, you have far more visualization after you have a properly

cleansed colon.

If we could go to the next slide.

So osmotic laxatives are a very common type of colonoscopy preparation, and SUTAB is an example of an osmotic laxative.

And these osmotic laxatives work in one of two ways: By either retaining water in the colon or drawing water into the colon. And they're typically comprised of poorly absorbed salts or inert compounds, and this leads to a high concentration of salt or compounds in the colon and then draws the water in.

The high concentration creates an osmotic pressure within the colon, and the body tries to balance that out by bringing more water into the colon, as shown in the figure. The increased water content then softens the stool and causes peristalsis, which is the contraction of the intestinal muscles which leads to purgation or emptying of the colon.

I'd like to talk a little bit about what the colonoscopy prep landscape looks like prior to the introduction of SUTAB.

If we could go to Slide 5.

There were a number of commercially-available options for colonoscopy preps prior to the introduction of SUTAB. As reflected in the table, each of these preps had some benefits as well as some significant drawbacks. The polyethylene glycol

preps or the PEG preps were and still are very commonly used. They're very effective and don't pose any major safety issue, however, they have two drawbacks. They require patients to ingest a large volume of liquid, and that liquid generally had a bad taste or a poor taste and that led to patient compliance issues.

The second type that was available are the phosphate solutions, predominantly sodium phosphate, and those aren't commonly used today because of serious safety concerns.

Now, these sodium phosphate products were available as tablets instead of the dissolved powder so they were more tolerated by patients; however, they could cause serious side effects which led to the FDA requiring a black box warning which we saw earlier and I'll discuss more a little later.

You then had the oral sulfate solutions, and this was the newest category. These were safe and effective, but they still suffered from some of the taste and volume issues of the PEG preps. And the one that I think you'll hear most about during this case is the SUPREP product, and we will talk about that in a little more detail.

And then fourth, you had kind of over-the-counter treatments. These were like Miralax and Gatorade. They weren't FDA approved, but they were still commonly used. They had a better taste than the other liquids, so they were better tolerated by patients, but they weren't as effective as the

FDA-approved preparations.

If we could go to the next slide.

As you saw in plaintiffs' presentation, there are four patents at issue. They're from the same family and have the same specification and they generally break down into two groups. You have the '656 and the '697 Patents, which are the composition patents; and the '864 and the '498 Patents, which are methods of treatment, method of administering the composition to cleanse the colon. And the priority date for all of the relevant patents is August of 2017.

If we could go to the next slide.

Just to give you a general overview of the asserted claims you're going to see. Composition claims, similar to Claim 1 of the '697 Patent; and then you'll see method of administration claims, method of cleansing the colon claims, similar to Claim 1 of the '498 Patent.

The commonality for all of the asserted claims is the recitation of three salts: Sodium sulfate, magnesium sulfate, and potassium chloride.

Now, the specific amounts or ranges of those ingredients will change, but those three salts are common across all of the asserted claims.

If we could go to the next slide.

So here we see those three components: The sodium sulfate, magnesium sulfate, and potassium chloride. When these

salts are dissolved in a liquid such as water, they break down into their positively and negative charged components, which are referred to as ions, and the positive and negative ions of each salt are illustrated in the structure column.

You'll see that the sodium sulfate and magnesium sulfate share the same negatively charged sulfate ion but they have different salt counter ions, the sodium and the magnesium.

THE COURT: Can you explain that because I don't understand what you're saying.

MR. ZIMMERMAN: Yes.

THE COURT: You should know -- if I don't understand, I'm just going to stop you and say I don't understand because it doesn't make sense to wait until you're done.

So can you just explain that to me again?

MR. ZIMMERMAN: Yes. So what you see is all of these salts have a positively charged piece and a negatively charged piece, and when you put this together as a solid, the charge cancels out and is zero. When you put them in water, they disassociate into pieces with a positive charge and pieces with a negative charge.

And so in the chart you see the positively charged piece for the first one is the sodium and it has a plus one; and then the counter ion or the second piece, which has the negative charges, the sulfate; and then for the magnesium sulfate you see the positively charged magnesium and then the

negatively charged sulfate again. So it's the same sulfate ion in solution from the sodium sulfate or the magnesium sulfate.

So if you were to be given the solution, you couldn't tell where the sulfates came from when they disassociated in the water.

Does that make sense?

THE COURT: A little bit.

MR. ZIMMERMAN: And then for the third component it's potassium chloride. And when it's dissolved in water, it breaks down into a positively charged potassium, which is indicated with the K, and the negatively charged chlorine atom. So when you put all of these components into solution and you mix them with water, what you see, it's no longer sodium sulfate, magnesium sulfate, and potassium chloride; it's ions of sodium, ions of magnesium, ions of sulfate, ions of potassium, and ions of chloride all floating around in the solution.

If we could go to the next slide.

What we're going to see on the next two slides is a table from an article from 2014 that summarized the available colonoscopy preparations that were available at that time. And as shown in the table, there are many repeat ingredients that show up in several of the preparations. It's a more comprehensive view of the landscape than the selected few we've seen earlier.

And so you'll see that there is potassium chloride widely used, sodium sulfate was widely used. And if we turn to the next slide, you'll see that the SUPREP kit introduced magnesium sulfate to the mix.

If we could go to Slide 11.

So as discussed on the previous slide, one type of commercially-available colonoscopy preparation which was introduced in 2010 was the SUPREP bowel kit. And this contained sodium sulfate, potassium sulfate, and magnesium sulfate. This regimen was a split-dose formulation where the patient would take half of the solution the night before the colonoscopy and the second half of the solution the morning of. And because of the way the claims are structured in the method claims, the split-dosing is going to become an issue in the case.

If we could proceed to Slide 12.

As discussed earlier, there were some tablet-based colonoscopy preparations on the market in 2017, specifically OsmoPrep and VISICOL. Both of these medications included sodium phosphate as their primary active ingredient and the tablets were better tolerated by patients who preferred tablets over ingesting large volumes of liquid that can be distasteful as well.

However, OsmoPrep and VISICOL had two major drawbacks that were suffered by both products. First, they included an

ingredient called microcrystalline cellulose, and that's an inactive ingredient or an excipient. And this ingredient doesn't dissolve in water and it would leave behind a residue in the colon which made it more difficult to visualize the colon during the colonoscopy process.

The second drawback was that sodium phosphate in these products could cause acute phosphate nephropathy, and this was a serious medical condition you heard about earlier that led to serious kidney disease.

So if we turn to the next slide, the FDA then put a black box warning on both of these products due to the safety concerns from sodium phosphate. And because of the safety concerns, the sodium phosphate tablets were not as widely used in 2017 despite their tolerability advantages compared to the liquid-based preps.

If we could turn to Slide 14.

One issue that you heard briefly from with the plaintiffs that will likely come up in the case relates to what are called electrolyte shifts, and these can occur from the preps from the colonoscopy.

Now, the electrolytes are salts or minerals in the blood or bodily fluid that carry an electrical charge, and these are often ions like the ions we discussed previously for the salts that are claimed in the asserted patents.

And one potential concern with these types of osmotic

laxatives was their propensity to cause patients to experience gains or losses in the electrolytes. And this is illustrated in the figure here which shows how osmotic laxatives can cause an influx of electrolytes from the body into the colon, leaving the body electrolyte depleted.

And these electrolyte shifts can cause health problems, particularly if they're at the large enough magnitude. And one key example of this is the sodium phosphate preps that we previously discussed. What they were causing was too much phosphate in the blood which was leading to the kidney issue.

And these electrolyte shifts were often addressed by adding salts to the colonoscopy prep in order to balance electrolytes. And you saw that most predominantly with the polyethylene glycol or PEG-based solutions.

If we could go to the next slide.

So the table that we see on Slide 15 shows an overview of the state of the electrolyte shifts with the various products that were available in 2017. And what we see is that the PEG and sulfate-based preps were not associated with any kind of measurable or effect-causing electrolyte shifts. And we did see those type of shifts in the sodium phosphate products.

If we could go to the next slide.

Another issue that will likely arise in the case

relates to the dosing or administration of the colonoscopy products and specifically what's often referred to as split-dosing. And split-dosing involves administering the colonoscopy prep in at least two separate doses separated by some amount of time. And you saw this in the claims of the method patents earlier.

Most commonly with these types of bowel preps what you saw was a first dose administered the night before the procedure and then a second dose the morning of, so the split-dosing was fairly common for these products. And what we've shown on the screen is the split-dosing regimen for both SUPREP and MOVIPREP.

Now, the split-dosing has been found to lead to two things: More effective colon cleansing because of the split administration, you get two doses of the medicine which makes it more effective by dividing them; and the second one was that this was the predominant approach for colonoscopy cleansing by 2017.

And why is this going to be important? If we go to the next slide, both of the method claims, the method patents, the '489 and the '864, require this type of split-dosing. As we've highlighted here, both of the methods of the claims require that the compositions are administered as a first dose and then a second dose that's administered later, both with multiple volumes of liquid.

If we go to the next slide.

Another issue that was discussed previously and will likely come up in the case is dissolution. And this relates to the process in which a substance is dissolved in a liquid and forms a solution. A very common example of this is dissolving table salt in water.

And dissolution testing measures the extent and the rate that a substance forms a solution. So essentially, how fast does it dissolve? And the figure on the slide here, which is similar to plaintiffs' figure, illustrates a common apparatus that's used for dissolution testing. It's the paddle apparatus. And as illustrated, the drug is placed within a volume of a liquid medium as the paddle blade rotates; and then the tense measures the amount of time it takes for the tablet to dissolve in the liquid. And the dissolution rate can be important because it can impact the bioavailability of the drug and the effectiveness of the drug.

If we go to the next slide.

This highlights why dissolution will likely be an issue in this case. Claims 17 and 18 of the '656 Patent contain specific dissolution requirements. Now, if we look at what the specifications say about dissolution, it says you can use the test methods provided in the United States Pharmacopoeia Volume 36, Section 711.

If we turn to that section, the Pharmacopoeia provides

general guidance on performing dissolution methods. For example, it explains how to set up the apparatus that can be used for the testing, such as the paddle.

Importantly, there are things that it doesn't tell you. The Pharmacopoeia doesn't tell you the paddle rotation speed, it doesn't tell you the dissolution media that's used, it doesn't place any specifics on the dissolution characteristics that a drug has to meet, and those aren't in the specification either.

And so the dispute between the parties there is going to be whether the disclosure in the patents is sufficient for the dissolution testing required.

If we go to the next slide.

Another topic that will come up in the case is the role of excipients, and we heard some about this earlier. In pharmaceutical products, an excipient is an inactive substance that provides the medium for delivering the drug. And the excipients are commonly referred to based on their function, that's how they're characterized, and the role they play in the tableting process.

For example, on the right side of the slide we have an excerpt from the patent specification which state that the disclosed compositions can include one or more excipients, and here they're characterized by function, binders, lubricants, grinders, et cetera.

In this case we'll be focusing on two particular functions of the excipient: One as a binder and one as a lubricant. As the name suggests, binders are the substances that help bind the powder mixture together to form the tablets. Lubricants are substances that reduce friction and prevent tablet material from sticking to the equipment as the tablets are compressed together. And this is important in getting uniformity for the tablets with respect to size and compression, which can impact how the tablets repeatedly function.

If we could turn to the next slide.

In the context of the tablets that were used for colonoscopy preparations, one of the important factors that was recognized in 2017 was to avoid insoluble excipients in the tablets. And we saw this earlier with respect to the microcrystalline cellulose in the sodium phosphate tablets. It wouldn't dissolve and would leave a residue that could obscure visualization of the colon. So one of the key factors at this time was to use excipients that were fully soluble or mostly soluble in water.

If we could turn to the next slide.

The two key excipients that will become at issue during the case are the binders and lubricants, and specifically the binder polyethylene glycol and the lubricant sodium caprylate. And as you'll see, both of these are claimed

in various claims of the asserted patents and the patents generally discuss them in the specification. But the discussion of them is limited to their function in terms of binder and lubricant.

If we could turn to the next slide.

Here we have an excerpt from the Handbook of Pharmaceutical Excipients that describes polyethylene glycol. As highlighted in the handbook, polyethylene glycol or PEG is a water-soluble excipient which is important for avoiding those residues that can obscure visualization during the colonoscopy.

And the handbook recognizes that high-molecular-weight PEGs or polyethylene glycols were known to enhance the effectiveness of tablet binders.

If we turn to the next slide, we address the second excipient. And here we have an excerpt from the Handbook of Pharmaceutical Excipients and one from the US Pharmacopeia National Formulary that provide information on the second excipient lubricant, sodium caprylate and sodium.

And sodium caprylate was discussed in the handbook as being used as a stabilizer during the production of albumin solutions, and it was also known that sodium caprylate could be dissolved in water, again, so it wouldn't leave the residue that impeded visualization during the colonoscopy.

And finally, Your Honor, I'd like to turn to the issue of turbidity. There was some discussion of it earlier. And

this is how cloudy a solution is. And turbidity is measured in Nephelometric Turbidity Units or NTU, as referred to in the specification. And that's a measure of how hazy the solution is. And as we can see on the top left side of the screen, you can see different kind of grades of visualization based on the NTU units.

And this testing is done by passing laser light through the solution, as shown in the bottom left corner.

If we turn to the next slide, the reason turbidity becomes important is because it is recited in Claim 20 of the '656 Patent. There is a brief discussion of turbidity in the patent, but no discussion of the parameters used of the turbidity testing, no disclosures of results of turbidity testing, no discussion of how to conduct the testing. And again, there will be a dispute between the parties as to definiteness and the amount of disclosure and was that sufficient.

Does Your Honor have any questions?

THE COURT: Not right now.

MR. ZIMMERMAN: Thank you very much.

THE COURT: Okay. So counsel, we're scheduled to do a hearing on October 29th. You'll have to remind me, because I'm in the midst -- I think in the next month or so I have three *Markman* hearings.

Are you just arguing or are you presenting testimony?

How many witnesses do you think you'll have?

MR. NOYES: Your Honor, we don't have any witnesses. It's just argument.

THE COURT: So you're both just going to argue. Okay. That's this case. All right.

MR. ZIMMERMAN: Yes, Your Honor.

THE COURT: So I will just tell you this -- you can both be seated. You should not presume that I know or understand anything. I have not had an ANDA case before. I've done patent cases before, I've done patent preliminary injunction cases before, but I have not done an ANDA case. So to the extent you think you don't want to insult me, I'd rather you insult me and start at a kindergarten level. Because as I said before, if I can't understand it, I can't decide it and it's not fair to either of you. And if I can't understand it, I will stop you and say please go back.

So the simpler you start, quite frankly, the better for me. This is extraordinarily helpful. One of the reasons I like to do this not on the same day, particularly when there are multiple patents, is because I read the briefs, then I -- which I usually can't make too much sense of. Then I listen to this, and this is extremely helpful, it starts to kind of make sense, and I'll go back and read the briefs again before you come in.

And not always, but my intent would probably be to,

depending on how I feel coming out, I may just rule from the bench or I may need more time to sort of think about it. Okay? So that's how I intend to proceed.

Anything else today from plaintiff?

MR. NOYES: Not from us, Your Honor. Thank you very much.

THE COURT: Anything else from the defendant today?

MR. ZIMMERMAN: Not from defendants, Your Honor, but I do have one question for the *Markman* hearing.

Do you want us to go plaintiff first and then defendant on all terms, or would you prefer term by term, plaintiff, defendant?

THE COURT: It is much easier for me -- so hopefully you'll agree -- to go term by term. Because I can listen to what you have to say, listen to what you have to say, ask whatever questions I have right then and there, then move on to the next one.

So I would prefer that when we have multiple issues like now. Is that agreeable to you both?

MR. NOYES: That's fine with us, Your Honor.

MR. ZIMMERMAN: Yes, Your Honor.

THE COURT: Thank you very much for asking. I do much prefer that.

Anything else? Do we still think -- I have from 10:00 to 1:00 blocked off for this. Do you think that's sufficient?

MR. NOYES: I think that's more than sufficient.

MR. ZIMMERMAN: I'm hopeful we can give the Court back time on that day.

THE COURT: I always like to have a little extra because I don't want to be rushed and if I or my clerks have questions.

So thank you for coming in early so you can accommodate the criminal matter. This has been extraordinarily helpful. I'll see you all in two weeks. We're adjourned.

THE COURTROOM DEPUTY: All rise.

(Matter adjourned at 1:24 p.m.)

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/S/ Sharon Ricci, RMR, CRR
Official Court Reporter

October 15, 2024
Date